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EXAMINER

MATTER, KRISTEN CLARETTE

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,854	Applicant(s) FISHER ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-10 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 8-10, and 13-23 is/are rejected.
- 7) ☐ Claim(s) 4 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the Request for Continued Examination filed on 11/20/2008. Claims 1, 7, and 13-22 have been amended and no claims have been added or cancelled. Currently, claims 1-4, 7-10, and 13-23 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-10, and 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, 14, 15, 16, and 17 all contain the language "the lid further comprises at least one lid opening wherein each lid opening is smaller." The limitation "each lid opening" lacks antecedent basis because there only has to be one lid opening, making the term each unclear as to how many lid openings there are. Examiner suggests changing "each" to --the at least one--.

Claims 2-4, 7-10, and 18-23 are dependant on a rejected claim base and are therefore rejected for the reasons outlined above with respect to claims 1 and 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3771

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan (US 6,772,756) in view of Frank (US 4,903,850).

Regarding claims 1, 13, 18, and 20, Shayan discloses a vaporizing device with a reservoir (40, 22) and a removable vapor-concentrating lid (12) with an opening (11) for the inhalation of a volatile substance (column 2, lines 50-55). Examiner contends that volatile is synonymous with effervescent. Shayan does not disclose that the vapor-concentrating lid comprises a central depressed area and a wall surrounding the central depressed area, said wall comprising a shaped depression, wherein the central depressed area and the shaped depression together conform approximately to a size and shape of a user's facial structure around the user's nose. However, Frank discloses a vaporizing device for inhalation of vapors by a user with a lid (14) having a centrally depressed area (see figures 1 and 2) and a plurality of lid openings (147) (see column 8, lines 1-15). The lid comprises a wall (outside of lid) and a central depressed area (entire inner area of the hood) surrounded by the wall, said wall comprising a shaped depression (at reference character 142 or 144 where the hood touches the user's face), wherein the central depressed area and the shaped depression together conform approximately to a size and shape of a user's facial structure around the user's nose (see Figure 1; the term "around" is relative and the bridge of the nose and jaw can reasonably be considered facial structure around the user's nose). The lid is adapted to concentrate a vapor from the reservoir at the user's nose (i.e., as opposed to letting the vapor disperse randomly into the ambient air). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Shayan's device with a

Art Unit: 3771

removable hood as taught by Frank for allowing the user to better direct the vapor into the nose for inhalation. Furthermore, although Frank does not explicitly disclose that the lid openings are smaller in area than the opening of the reservoir, examiner contends that is an obvious design consideration to one of ordinary skill in the art to size the lid openings (147) such that they would be smaller than the opening of the reservoir, since such a modification would have involved a mere change in the size of a component inasmuch as the lid openings still allowed ambient air and exhaled air to flow in and out of the hood. See also *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 2, the reservoir disclosed by Shayan can be considered a cup (see Figure 3).

Regarding claim 3, Shayan discloses that the device can be made of a plastic (column 4, lines 59-60) and that the receptacle and top can be made integrally (column 6, lines 50-55). However, to the extent that to the extent that Shayan is silent as to the material of the reservoir specifically, it is considered an obvious design choice to use a material suitable for a given use. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claims 14-17, the modified device disclosed by Shayan and Frank has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim. Depending on the type of pharmaceutical substance added to the reservoir, any number of

Art Unit: 3771

different conditions could be treated. Furthermore, the use of hot water as a carrier (or to be vaporized) would generate steam (i.e., humidified air).

Regarding claims 19 and 21, the at least one lid opening disclosed by Frank et al. can be considered centrally located in the lid (see Figure 1 in which the opening 147 is located half-way up/centrally on the side of the lid).

Regarding claims 22 and 23, the at least one lid opening disclosed by Frank et al. is located in the central depressed area of the lid because it goes all the way through the wall and into the central depressed area of the lid (i.e., the inner sides and the bottom of the lid of Frank et al. are all considered to be the central depressed area).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan and Frank as applied to claim 1 above, and further in view of Ninkov (US 2003/0225003).

Shayan is silent as to the specifics of the volatile substance, although Shayan does disclose that the volatile substance can be emulsions or liquids (column 6, lines 40-45). Ninkov discloses useful therapeutic compositions for oral inhalation to treat infection that include liquids and emulsions of polyethylene glycol (paragraphs 0095 and 0137). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyethylene glycol emulsion in the modified device disclosed by Shayan and Frank in order to treat a given infection.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan and Frank as applied to claim 1 above, and further in view of Silten (US 2,033,489).

Art Unit: 3771

Shayan is silent as to the specifics of the volatile substance. Silten discloses a device for the inhalation of vapors comprising substances with excipients (column 6, lines 55-60) and dyes (column 1, lines 40-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used substances including excipients and dyes as taught by Silten in the modified device of Shayan and Frank in order treat various respiratory diseases or to allow a user to see the liquid being vaporized.

Allowable Subject Matter

Claims 4 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 11/20/2008 regarding the Frank et al. and Shayan references have been fully considered but they are not persuasive.

Applicant's arguments on pages 11 and 12 with respect to the size of the vents of Frank et al. are somewhat confusing. It appears that the applicant is calling the top opening (140) of the lid of Frank et al. the "at least one lid opening." However, in the Action, the lid openings of Frank et al. are considered the vents (147) located on the sides of the lid (see figure 1). Therefore, reducing the size of these vents to be smaller than an opening of the reservoir would have been an obvious design consideration so long as the vents (147) were still able to allow ambient air into the lid and to exhaust exhaled air/vapor (i.e., the size of these openings is

Art Unit: 3771

irrelevant to the size of the opening 140 for resting a user's face into as long as vapor is able to vent to ambient air).

In response to applicant's arguments that the hood of Frank et al. does not concentrate vapor at a user's nasal area, examiner respectfully maintains that as seen in Figure 1, vapor is concentrated at the nose and mouth of a user as opposed to dispersing uncontrollably into the ambient air. The limitation "around" a user's nose is a relative term and as discussed above, the top of the nose and the jaw can be considered to lie around the nose and thus read on the instant claims.

Examiner notes that the amendment of 11/20/2008 was sufficient to overcome the Nielsen in view of Fuisz et al. rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 3771

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771